

REMARKS

Claims 187-201 and 217-231 were pending in the application. Claims 187-201 and 217-231 have been canceled. This cancellation has been made without prejudice, and the Applicants reserve the right to pursue the subject matter in the cancelled claim in continuing applications. Claims 232-233 have been added. Support for new claims 232 and 233 is found in the specification in paragraphs [0026]-[0050], and throughout the specification. It is submitted that no new matter has been introduced by the present amendments and entry of the same is respectfully requested. By the amendments, Applicants do not acquiesce to the propriety of any of the Examiner's rejections and do not disclaim any subject matter to which Applicants are entitled. *Cf. Warner Jenkinson Co. v. Hilton-Davis Chem. Co.*, 41 U.S.P.Q.2d 1865 (U.S. 1997).

I. Rejections under 35 U.S.C. § 102(e)

Claims 187-190, 193, 195, 196 and 198 are rejected under 35 U.S.C. § 102(e) as being anticipated by Bydlon *et al.* (U.S. Pat. Appln. No. 2003/0050341, "Bydlon"). Office Action at page 2.

In order to support an anticipation rejection under 35 U.S.C. § 102, the Examiner must illustrate that each and every element of a claimed invention was disclosed within a single prior art reference. *In re Bond*, 15 U.S.P.Q.2d 1566, 1567 (Fed. Cir. 1990). A claimed invention is anticipated only when it is "known to the art in the detail of the claim." *Karsten Manufacturing Corp. v. Cleveland Golf Co.*, 242 F.3d 1376, 1383 (Fed. Cir. 2001). In other words, not only must the limitations of claim be shown in a single prior art reference, the limitations must be "arranged as in the claim." *Id.* Bydlon does not disclose a composition with each and every element of the claimed invention.

Claims 187-190, 193, 195, 196 and 198 have been canceled, without prejudice. New claims 232 and 233 recite that "iron consists of non-chelated iron in an amount of 43 mg to 80 mg." Bydlon does not teach a composition where iron is present in these amounts. Therefore Bydlon does not teach each and every element of the claimed invention.

Accordingly, Applicants respectfully request that any rejections of claims 187-190, 193, 195, 196 and 198 under 35 U.S.C. § 102(e) over Bydlon be reconsidered and withdrawn and that new claims 232-233 are free of the prior art and are in condition for allowance.

II. Rejections under 35 U.S.C. § 103

Claims 187-201, and 217-231 are rejected under 35 U.S.C. § 103(a) as allegedly unpatentable over Bydlon *et al.* (U.S. Pat. Appln. No. 2003/0050341, "Bydlon") in view of Moshlyedi (U.S. Pat. No. 5,770,215, "Moshlyedi") and one of The Merck Index or Briggs *et al.* (U.S. Pat. No. 4,752,479, "Briggs"). Applicants respectfully traverse.

To maintain a proper rejection under 35 U.S.C. § 103, the USPTO must meet four conditions to establish a *prima facie* case of obviousness. First, the USPTO must show that the prior art suggested to those of ordinary skill in the art that they should make the claimed composition or device or carry out the claimed process. Second, the USPTO must show that the prior art would have provided one of ordinary skill in the art with a reasonable expectation of success. Both the suggestion and the reasonable expectation of success must be adequately founded in the prior art and not in an applicant's disclosure. Third, the prior art must teach or suggest all the claim limitations. *In re Vaack*, 20 U.S.P.Q.2d 1438, 1442 (Fed. Cir. 1991). Fourth, if an obviousness rejection is based on some combination of prior art references, the USPTO must show the suggestion, teaching, or motivation to combine the prior art references. *In re Dembiczak*, 50 U.S.P.Q.2d 1614, 1617 (Fed. Cir. 1999).

Claimed ranges must "overlap or lie inside ranges disclosed by the prior art" for a *prima facie* case of obviousness to exist. *In re Wertheim*, 541 F.2d 257, 191 USPQ 90 (CCPA 1976); *In re Woodruff*, 919 F.2d 1575, 16 USPQ2d 1934 (Fed. Cir. 1990). Further, if the reference's disclosed range is so broad as to encompass a very large number of possible distinct compositions, this might present a situation analogous to the obviousness of a species when the prior art broadly discloses a genus. *In re Peterson*, 315 F.3d 1325, 1330, 65 USPQ2d 1379, 1382-83 (Fed. Cir. 2003). Bydlon does not teach or suggest a composition where iron is present in the claimed amounts, and Moshlyedi, in combination with the Merck Index or Briggs do not make up for this deficiency.

Claims 187-201 and 217-231 have been cancelled, without prejudice. Bydlon does not teach or suggest the iron concentrations recited in new claims 232 and 233. New claims 232 and 233 recite that "iron consists of non-chelated iron in an amount of 45 mg to 80 mg." The priority document of Bydlon, U.S. Provisional Patent Application No. 60/318,857, filed September 12, 2001, only relates to a composition containing iron from 14 mg to 42 mg. The amounts of iron recited in new claims 232 and 233 do not overlap or lie inside that recited in

Bydlon. U.S. Provisional Patent Application No. 60/318,857, page 9, line 32. Therefore, U.S. Provisional Patent Application No. 60/318,857 cannot be used to make a *prima facie* case of obviousness of the iron ranges recited in new claims 232 and 233.

Further, Applicants respectfully submit that the Bydlon patent application publication, without priority to U.S. Provisional Patent Application No. 60/318,857, is not prior art to the Applicants' invention. The instant Bydlon patent application publication was filed on September 12, 2002 and published on March 13, 2003. The Declaration Of John A. Giordano Under 37 C.F.R. §1.131 ("the Giordano Declaration") and its associated evidence submitted with the Response of February 11, 2005, establish that the claimed invention was reduced to practice before May 2, 2002. Therefore, the Bydlon, U.S. Pat. Pub. No. 2003/0050341, is not prior art to the Applicant's application.

The secondary references cited by the Examiner do not make up for this deficiency of Bydlon. Moshyedi does not make up for this deficiency as it relates to iron of at least 5% or 10% of the RDA per unit dose of 6 mg to 30 mg: essentially 0.3 mg to 30 mg. Moshyedi, column 7, lines 17-27. The Merck Index, pages 5541, 893, 1464, 1579, 1580, do not make up for this deficiency because it does not provide any iron ranges for such compositions.

Further, there is no motivation to combine Moshyedi with Bydlon or Briggs. Moshyedi relates to compositions comprising aspirin and at least one vitamin. Neither Moshyedi, Bydlon, Briggs nor the Merck Index teach or suggest making a nutritional supplement with the amounts of vitamins and minerals disclosed in an aspirin therapeutic for cardiac care patients to be used to supplement the diets of pregnant or lactating women, and do not provide an expectation of success in this combination. Further, there would be no motivation or expectation of success to combine Bydlon, Moshyedi and Briggs as they all are tailored to patients with different conditions: the first relates to a nutritional supplement tailored to expectant and new mothers and children, the second relates to a aspirin-contained cardiac care therapeutic, and the last relates to vitamin supplements for the treatment of anemia.

Briggs teaches away for the compositions in new claims 232 and 233 and removes any motivation to combine with Bydlon or Moshyedi. New claims 232 and 233 recite "active ingredients combined in an intimate admixture with a suitable carrier." Briggs relates to dietary supplement formulations that have as their object the ability of the host to absorb iron with maximum efficiency and with reduced gastrointestinal side effects. Briggs, column 1,

lines 52-56. Briggs approaches this object with formulations where the calcium and/or magnesium are in a layer surrounding the iron in order to release them separately in the gastrointestinal tract. Briggs, column 2, lines 11-37 and claim 1. Therefore, one of ordinary skill in the art upon reading Briggs would not combine Briggs with Bydlon or Moshyedi to make the composition of the present invention because Briggs teaches away from mixing the calcium and/or magnesium with the iron components, and the compositions of the claimed invention have all of the components of the composition mixed together. Further, one of ordinary skill in the art would also not be motivated to take an iron concentration described in Briggs, which is specifically tailored to the layered, slow release formulation, and apply it to a nutritional supplement without such characteristics and this would not have an expectation of success in the combination. Finally, the combination of Briggs with Bydlon or Moshyedi to make the claimed invention would change the principle of operation of the Briggs invention by removing the critical formulatory features, therefore one of ordinary skill in the art would not be motivated to make the combination.

Accordingly, Applicants respectfully request that any rejections of claims 187-201, and 217-231 under 35 U.S.C. § 103(a) over Bydlon, in view of Moshyedi and one of the Merck Index or Briggs be reconsidered and withdrawn and Applicants submit that new claims 232 and 233 are free of the prior art and are in condition for allowance.

III. Rejections under Non-Statutory Type Double Patenting

A. Claims 187-201 are provisionally rejected under the doctrine of obviousness-type double patenting as being unpatentable over claims 187-207 of copending Application No. 11/296,210. Office Action at page 6. Applicants respectfully traverse.

The Examiner has instructed that a terminal disclaimer in compliance with 37 C.F.R. §1.321(c) may be used to overcome an actual or provisional rejection based on non-statutory double patenting ground. Without addressing the propriety of the Examiner's rejection, and specifically the Examiner's interpretation of what the cited references teach or suggest, Applicants respectfully defer addressing the present rejection until there is allowable subject matter in the present application. Only then is it proper to assess the propriety of the Examiner's rejection in view of the allowed claims. Accordingly, Applicants respectfully

request reconsideration of the present rejections when claims are found otherwise allowable in the present application.

B. Claims 187-201 and 217-231 are provisionally rejected under the doctrine of obviousness-type double patenting as being unpatentable over claims 187-207 of copending Application No. 11/296,210. Office Action at page 7. Applicants respectfully traverse.


The Examiner has instructed that a terminal disclaimer in compliance with 37 C.F.R. §1.321(c) may be used to overcome an actual or provisional rejection based on non-statutory double patenting ground. Without addressing the propriety of the Examiner's rejection, and specifically the Examiner's interpretation of what the cited references teach or suggest, Applicants respectfully defer addressing the present rejection until there is allowable subject matter in the present application. Only then is it proper to assess the propriety of the Examiner's rejection in view of the allowed claims. Accordingly, Applicants respectfully request reconsideration of the present rejections when claims are found otherwise allowable in the present application.

CONCLUSION

Applicants have properly and fully addressed each of the Examiner's grounds for rejection. Applicants submit that the present application is now in condition for allowance. If the Examiner has any questions or believes further discussion will aid examination and advance prosecution of the application, a telephone call to the undersigned is invited. If there are any additional fees due in connection with the filing of this amendment, please charge the fees to undersigned's Deposit Account No. 50-1067. If any extensions or fees are not accounted for, such extension is requested and the associated fee should be charged to our deposit account.

Respectfully Submitted,

September 21, 2006



Don J. Pelt
Reg. No. 33,754

Preston Gates Ellis & Rouvelas Meeds LLP
1735 New York Avenue, NW, Suite 500
Washington, DC 20006
Telephone: (202) 628-1700
Facsimile: (202) 331-1024